

Commonwealth of Virginia



PROPOSED REGULATIONS

Title of Regulations: 18 VAC 110-20-10 et seq.

**Statutory Authority: Virginia Acts of Assembly—2002 Session
Chapters 411, 632, 666, and 707**

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18 VAC 110-20-240. Manner of maintaining records, prescriptions, inventory records.

- A. Each pharmacy shall maintain the inventories and records of drugs as follows:
1. Inventories and records of all drugs listed in Schedules I and II shall be maintained separately from all other records of the pharmacy.
 2. Inventories and records of drugs listed in Schedules III, IV, and V may be maintained separately or with records of Schedule VI drugs but shall not be maintained with other records of the pharmacy.
 3. All records of Schedule II through V drugs shall be maintained at the same location as the stock of drugs to which the records pertain except that records maintained in an off-site data base shall be retrieved and made available for inspection or audit within 48 hours of a request by the Board or an authorized agent.
 4. In the event that an inventory is taken as the result of a theft of drugs pursuant to § 54.1-3404 of the Drug Control Act, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date.
 5. All inventories required by § 54.1-3404 shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening of business or after close of business. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.
 6. All records required by this section shall be filed chronologically.
- B. Prescriptions.
1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing.
 2. Schedule II drugs. Prescriptions for Schedule II drugs shall be maintained in a separate prescription file.
 3. Schedule III through V drugs. Prescriptions for Schedule III through V drugs shall be maintained either in a separate prescription file for drugs listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescriptions of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one inch high and filed in the prescription file for drugs listed in the usual consecutively numbered prescription file for Schedule VI drugs. However, if a pharmacy employs an automated data processing system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by

prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

C. Chart Orders.

1. A chart order written for a patient in a hospital or long term care facility, a patient receiving home infusion services, or a hospice patient pursuant to §54.1-3408.01 (A) of the Code of Virginia shall be exempt from having to contain all required information of a written prescription provided:
 - a. This information is contained in other readily retrievable records of the pharmacy; and
 - b. The pharmacy maintains a current policy and procedure manual that sets out where this information is maintained and how to retrieve it and the minimum requirements for chart orders consistent with state and federal law and accepted standard of care.
2. A chart order may serve as the hard-copy prescription for those patients listed in subdivision 1 of this subsection.
3. Requirements for filing of chart orders.
 - a. Chart orders shall be filed chronologically by date of initial dispensing with the following exception: If dispensing data can be produced showing a complete audit trail for any requested drug for a specified time period and each chart order is readily retrievable upon request, chart orders may be filed using another method. Such alternate method shall be clearly documented in a current policy and procedure manual.
 - b. If a single chart order contains both an order for a Schedule II drug and one or more orders for a drug in another schedule, where the Schedule II drug is not floor-stocked, but is dispensed from the pharmacy pursuant to this order for the specific patient, the original order must be filed with records of dispensing of Schedule II drugs and a copy of the order placed in the file for other schedules.

18 VAC 100-20-255. Other dispensing records.

Pursuant to §54.1-3412, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

18 VAC 110-20-275. Delivery of dispensed prescriptions.

- A. Pursuant to § 54.1-3420.2 (B), in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver prescriptions to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.
2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:
 - a. A description of how each pharmacy will comply with all applicable federal and state law;
 - b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;
 - c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;
 - d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;
 - e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;
 - f. The policy and procedure for ensuring accuracy and accountability in the delivery process;
 - g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions which are not delivered to the patient; and
 - h. The procedure for informing the patient and obtaining consent if required by law for using such a dispensing and delivery process.
3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18 VAC 110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.
2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:
 - a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;
 - b. Procedure for providing counseling;
 - c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;
 - d. The procedure for assuring confidentiality of patient information; and
 - e. The procedure for informing the patient and obtaining consent if required by law for using such a delivery process.
3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in accordance with 18 VAC 110-20-710.

18 VAC 110-20-320. Refilling of Schedule III through VI prescriptions.

- A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.
 1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with § 54.1-3412 and 18 VAC 110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.
 2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:
 - a. Each partial dispensing is recorded in the same manner as a refilling;
 - b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and
 - c. No dispensing occurs after six months after the date on which the prescription order was issued.
- B. A prescription for a drug listed in Schedule VI shall be refilled only as expressly authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in § 54.1-3410 C or subdivision § 54.1-3411 of the Code of Virginia.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than two years after the date on which it was issued.

- C. As an alternative to all manual record-keeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18 VAC 110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription ~~for~~ drugs dispensed.
- D. Authorized refills of all prescription drugs may only be dispensed in reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment.

18 VAC 110-20-400. Returning of drugs and devices.

- A. Drugs or devices may be accepted for return or exchange by any pharmacist or pharmacy for resale after such drugs and devices have been taken from the premises where sold, distributed, or dispensed provided such drug or devices are in the manufacturer's original sealed containers or in unit dose container which meets the U.S.P. N.F. Class A or Class B container requirement and provided such return or exchange is consistent with federal law and regulation. in accordance with the provisions of §54.1-3411.1. Devices may be accepted for return or exchange provided the device is in manufacturer's original sealed packaging.
- B. Any pharmacy accepting drugs returned from nursing homes for the purpose of re-dispensing to the indigent, free of charge, shall maintain a copy of a written agreement with the nursing home in accordance with §54.1-3411.1 (B) and a current policy and procedure manual describing the following:
 - 1. Method of delivery from the nursing home to the pharmacy and of tracking of all prescription medications;
 - 2. Procedure for determining the suitability and integrity of drugs for re-dispensing to include assurance that the drugs have been stored according to official compendial standards; and
 - 3. Procedure for assigning a beyond-use date on re-dispensed drugs.

~~18 VAC 110-20-430. Chart order.~~

~~A chart order for a drug to be dispensed for administration to an in patient in a hospital shall be exempt from the requirement of including all elements of a prescription as set forth in § 54.1-3408 and § 54.1-3410 of the Code of Virginia. A hospital pharmacy policy and procedures manual shall set forth the minimum requirements for chart orders consistent with federal and state law.~~

18 VAC 110-20-530. Pharmacy's responsibilities to long term care facilities.

The pharmacy serving a long-term care facility shall:

- 1. Receive a valid order prior to the dispensing of any drug.

2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.
3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.
4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.
5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.
6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.
7. Provide for the disposition of discontinued drugs under the following conditions:
 - a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for re-dispensing to the indigent if authorized by § 54.1-3411.1 and 18 VAC 110-20-400, or destroyed by appropriate means in compliance with any applicable local, state, and federal laws and regulations.
 - b. Drug destruction at the pharmacy shall be witnessed by the pharmacist-in-charge and by another pharmacy employee. Drug destruction at the facility shall be witnessed by the Director of Nursing or, if there is no Director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.
 - c. A complete and accurate record of the drugs returned and/or destroyed shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.
 - d. All destruction of the drugs shall be done within 30 days of the time the drug was discontinued.
8. Ensure that appropriate drug reference materials are available in the facility units.
9. Ensure that a monthly review of a drug therapy by a pharmacist is conducted for each patient in long term care facilities except those licensed under Title 63-1 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

18 VAC 110-20-730. Requirements for practitioner of medicine or osteopathy in free clinics.

- A. Any practitioner of medicine or osteopathy who provides controlled substances, which have been donated pursuant to §54.1-3301 (11) of the Code of Virginia shall apply for a controlled substances registration.
- B. A practitioner in a free clinic may only accept donated drugs pursuant to this registration if they are donated by an entity or practitioner who holds a current active license, permit, or registration issued by the board authorizing the dispensing or distribution of drugs.
- C. A practitioner shall store such donated drugs for dispensing in compliance with the storage and security requirements set forth in 18 VAC 110-20-710, and a drug which has exceeded its expiration date shall be not be dispensed. A practitioner shall be responsible maintaining and complying with a written procedure for reviewing inventory for the purpose of removing expired drugs.
- D. A practitioner shall package any dispensed drugs in accordance with the provisions of §§ 54.1-3426 and 54.1-3427 of the Code of Virginia and sections 18 VAC 110-20-340 and 18 VAC 110-20-350.
- E. A practitioner shall label any dispensed drugs in accordance with the provisions of §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and section 18 VAC 110-20-330 to include the free clinic name and address, name of the prescriber, patient name, date of dispensing, drug name to include the generic name if the drug has a single active ingredient, drug strength if applicable, quantity, and directions for use.
- F. A practitioner shall comply with all recordkeeping requirements of § 54.1-3404 of the Code of Virginia and shall also maintain a chronological record of all Schedule II-VI drugs dispensed showing patient name and address, date of dispensing, drug name, strength, and quantity dispensed, and name or initials of the dispensing practitioner.
- G. A practitioner under this section may enter into a contract or written agreement with a pharmacy whereby the pharmacy maintains all or part of the donated stock, dispenses the prescription pursuant to a written prescription by a prescriber at the free clinic, and delivers the dispensed prescription to the free clinic for pick up by the patient in accordance with subsection C of 18 VAC 110-20-275.